IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS BEAUMONT DIVISION

MARK A. BARRY, MD,		§	
	Plaintiff,	§ § Ci	vil Action No. 1:14-104-RC
v.		§ 2	
MEDTRONIC, INC.,		§ Ju	lge Ron Clark
	D C 1	§	
	Defendant.	Š	

MEDTRONIC, INC.'S BENCH MEMORANDUM ON EXPERIMENTAL USE AND PATIENT NOTIFICATION

ARGUMENT

Medtronic Inc. ("Medtronic") files this memorandum in support of its contention that it should be entitled to question Dr. Barry about his assertions that certain procedures he performed in 2002 or 2003 were experimental uses of his patented invention. The Federal Circuit has held that a patentee urging that certain uses were "experimental"—and therefore not invalidating under 35 U.S.C. § 102(b)—must show "that customers [were] made aware of the experimentation." *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1186 (Fed. Cir. 1993). Accordingly, Medtronic should be entitled to ask Dr. Barry about whether he informed patients that he was experimenting.

Where a defendant puts forth evidence establishing pre-critical date public uses or sales, then the patentee may seek to rebut the public use or sales by demonstrating that they were for an

¹ This memorandum is also responsive to this Court's order regarding Dr. Barry's fourth motion *in limine*. Dkt. 378 at 1.

experimental purpose. See, e.g., Petrolite Corp. v. Baker Hughes Inc., 96 F.3d 1423, 1425 (Fed. Cir. 1996); Sinskey v. Pharmacia Ophthalmics, Inc., 982 F.2d 494, 499 (Fed. Cir. 1992), abrogated on other grounds by Pfaff v. Wells Elecs., Inc., 525 U.S. 55 (1998).

Medtronic will establish that Dr. Barry repeatedly used his claimed method on patients in 2002 and 2003, that Dr. Barry received his regular rate of pay on these occasions, and that others received remuneration as well—actions that constitute both an invalidating public use and sales under § 102(b). Indeed, Dr. Barry has *already testified* on direct examination that he used the patented method on patients prior to the critical date of December 30, 2003. *See*, *e.g.* Day 1 Tr. at 190:3-6 (Dr. Barry admitting that he used "derotation levers with the three slots in the handle" in August 2003); *id.* at 195:12-16 (same in October 2003); *id.* at 203:19-205:4 (acknowledging at least 19 surgeries using patented invention). And Dr. Barry has already made clear his intention to argue that his public use and sale of the patented invention was an "experimental use" that would allow him to escape the § 102(b) bar. *See*, Dkt. 350-1 at 46-47 (Dr. Barry's proposed jury instruction on experimental use).

"[T]he assertion of experimental sales, *at a minimum*, requires that customers must be made aware of the experimentation." *Paragon Podiatry*, 984 F.2d at 1186; *In re Dybel*, 524 F.2d 1393 (CCPA 1975) ("Appellant's failure to communicate to any of the purchasers or prospective purchasers of his device that the sale or offering was for experimental use is fatal to his case."); *Small v. Nobel Biocare USA, LLC*, 2013 WL 3972459, at *13 (S.D.N.Y. Aug. 1, 2013) (finding no experimental use where "procedure lacked the traditional indicia of formal experimentation sufficient to warrant negation of the public use bar. [Patentee]'s patient was never informed that the procedure was experimental, nor was he asked to sign any additional paperwork beyond the

standard forms required by the N.Y.U. dental clinic."). This is so because the disclosure of experimental intent provides contemporaneous evidence of the inventor's experimental purpose and control of his invention, while a lack of any such disclosures cuts against any such argument. Ultimately, "after-the-fact testimony of an inventor's subjective 'experimental intent' is entitled to minimal weight" in the face of a clear public use. *Sinskey*, 982 F.2d at 499.

Accordingly, Medtronic should be entitled to question Dr. Barry and any other witnesses about whether he informed patients of the alleged experimental nature of the use of the patented invention, which he admits occurred more than one year before his earliest patent application filing. Medtronic respects the ruling of the Court and has no intention of drawing inflammatory comparisons of Dr. Barry through this testimony, and understands the Court's concern on this issue. Day 1 Tr. 113:12-21. Rather, Medtronic simply seeks to establish, in line with the authorities cited above, that Dr. Barry has failed to satisfy the experimental exception to public use because he did not inform his patients, medical staff or others with whom he was doing business that the approximately twenty procedures in question were experimental.

CONCLUSION

For all the foregoing reasons, Medtronic respectfully requests that the Court allow it to question Dr. Barry and the other trial witnesses about whether he informed patients on whom he performed surgeries in 2002 and 2003 that the surgeries were experimental.

Dated: November 4, 2016 Respectfully submitted,

By: /s/ Clyde M. Siebman

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on November 4, 2016.

/s/ Clyde M. Siebman Clyde M. Siebman